

# Don't Swallow Benadryl Itch Stopping Gel: Use on Skin

Swallowing an over-the-counter medication meant to be rubbed on the skin can have harmful effects, warns the Food and Drug Administration (FDA).

FDA has received reports of serious side effects—such as unconsciousness, hallucinations, and confusion—in people who mistakenly swallowed Benadryl Extra Strength Itch Stopping Gel.

Although there are other over-the-counter liquid Benadryl products intended to be swallowed, Benadryl Extra Strength Itch Stopping Gel is NOT one of them. It is a topical product meant for use only on the skin.

Benadryl Extra Strength Itch Stopping Gel is safe and effective when used on the skin as directed. People who swallow it can receive dangerously large amounts of the active ingredient, diphenhydramine.

## Advice for Consumers

- In your home, store products for the skin separately from products that should be swallowed.
- Read the “Drug Facts” box on the product’s label to identify active ingredients, directions for use, and warnings before using any over-the-counter drug product.





- Check with a health care professional such as your doctor or pharmacist if you are not sure which over-the-counter product is right for you.
- Report any side effects from the use of over-the-counter products to FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, by fax, or by phone.
  - Online at [www.fda.gov/Safety/MedWatch/](http://www.fda.gov/Safety/MedWatch/)
  - Regular Mail: Use postage-paid, pre-addressed FDA form 3500 available at [www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm](http://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm)
  - Fax: 1-800-FDA-0178
  - Phone: 1-800-332-1088

To help consumers recognize that Benadryl Extra Strength Itch Stopping Gel is meant for use on the skin, the manufacturer, Johnson and Johnson, has

- changed the product label to add

a new, prominent statement "For Skin Use Only"

- attached a sticker to the cap of the product that says "For Skin Use Only"
- initiated consumer studies to better understand factors that may contribute to consumers mistakenly swallowing Benadryl Extra Strength Itch Stopping Gel



### Other Topical Gels

Many pharmacies and grocery stores sell other diphenhydramine topical gels that look very similar in packaging to Benadryl Extra Strength Itch Stopping Gel. Consumers should not swallow these products either. Swallowing them can also result in serious side effects.

FDA encourages manufacturers of similar products to follow Johnson and Johnson's example and adopt similar changes to their labeling and packaging.

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